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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,351	04/21/2004	Manja Ahola	TUR-140-A	6705
32954 7590 01/16/2007 JAMES C. LYDON 100 DAINGERFIELD ROAD SUITE 100 ALEXANDRIA, VA 22314			EXAMINER TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/16/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/828,351

Applicant(s)

AHOLA ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28, 31 and 32 is/are rejected.
- 7) ☒ Claim(s) 29 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>01/03/07</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/17/06 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-28, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducheyne et al. US 5,591,453, in view of Einarsrud et al. US WO 92/20623.

Ducheyne teaches a controlled release matrix carrier comprising silica based glass prepared by a sol-gel process (see abstract; and column 8, lines 43-67). The silica based glass further comprising calcium (column 10, lines 8-10). Ducheyne further teaches biologically active molecules are incorporated within the matrix (see abstract). Biologically active molecules include drugs, growth factors, cytokines, antibiotics, anti-inflammatory agent, and analgesics (column 9, lines 54-64). Ducheyne also teaches the matrix is suitable for administration as an implant in the form of granules, discs, or monoliths (column 10, lines 8-16).

Ducheyne does not teach the silica-xerogel. However, silica-xerogel is well known as silica based glass compound in pharmaceutical art. To be more specific, Einarsrud teaches silica-xerogel has high porosity and therefore suitable to be used as a composite materials and carrier for catalyst and liquids (page 1, lines 25-27). Thus, it would have been obvious to one of ordinary skill in the art to modify the teaching of Ducheyne using the silica-xerogel as a silica based glass to obtain the claimed invention, because Ducheyne teaches the use of silica based glass in a composite composition (column 6, lines 32-34), because Ducheyne teaches the desire to use porous material (column 10, lines 8-21), because Ducheyne teaches using a sol-gel process to obtain a microporosity sol-gel glass that can control the release of the biologically active molecules (column 9, lines 5-19), because Ducheyne teaches silica-

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based includes silicon oxide, and other oxides (column 9, lines 50-52), and because Einarsrud teaches using high porosity material such as silica xerogel as a composite material.

It is noted that the cited references do not explicitly teach a substantially constant release rate of bioactive agent by complete dissolution of the silica xerogel. However, the examiner is unable to determine whether or not the release of active agent taught by Ducheyne cannot be achieved by the dissolution of the silica base glass matrix.

Therefore, the burden of proof is shifted to applicant to show that the silica-base glass matrix taught by Ducheyne does not release the active agent by dissolution of the silica base glass matrix. *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). This is because Ducheyne does teach a silica-base glass matrix that is degradable, and the release rate can be controlled by rapid or slow degradation of the carrier (column 14, lines 35-39). Furthermore, Ducheyne also teaches a steady state release rate (column 15, lines 10-12).

Response to Arguments

Applicant's arguments filed 10/30/06 have been fully considered but they are not persuasive.

Applicant argues that the cited combination of references fails to raise a *prima facie* case of obviousness against the claimed method because the cited references fail to disclose or suggest the "total dissolution of the silica-xerogel carrier" feature of the

claimed method. Instead, Ducheyne's controlled release is achieved primarily by diffusion through the pores of the silica-base glass.

However, in response to the applicant's arguments, as discussed above, it would have been obvious to one of ordinary skill in the art to modify the teaching of Ducheyne to obtain the claimed invention, because Ducheyne teaches a silica-base glass that is degradable, and because a steady state release rate can be achieved. Applicant is invited to show that the silica-base glass matrix taught by Ducheyne does not release the active agent by degradation/dissolution. Moreover, assuming *arguendo* that the silica-base glass matrix taught by Ducheyne does not release the active agent by degradation of the matrix, the examiner is unable to determine the unexpected results over the claimed invention, because Ducheyne teaches using similar silica-base glass made by the same method, namely, the sol-gel method to obtain the advantageous results desired by the applicant, *e.g.*, controlled drug release over time, (column 18, lines 36-46).

Applicant argues that the deficiencies of Ducheyne are not remedied by the additional disclosure of Einarsrud, because Einarsrud does not teach the complete dissolution feature of the claimed method of administering a biologically active agent into a human or animal body, but its main emphasis is on obtaining gels with high porosity. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of

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the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Einarsrud is relied upon solely for the teaching that silica-xerogel can be used as a composite materials or carrier due to its porosity (page 1, lines 21-27).

Claims Allowable

Claims 29 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

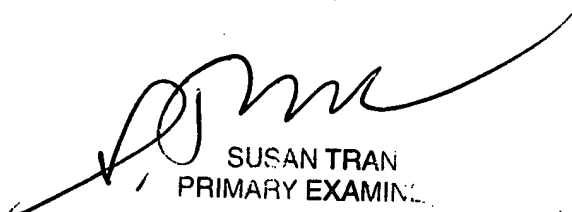
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SUSAN TRAN
PRIMARY EXAMINER

S. Tran
Patent Examiner
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